



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 11 2004

Mr. George M. Tancos
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515-0070

Re: k023657
Trade/Device Name: AscensiaTMContourTM Diabetes Care System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; LFR
Dated: February 14, 2003
Received: February 19, 2003

Dear Mr. Tancos:

This letter corrects the SE Letter K023657 stamp dated May 12 2003. In the previous letter the Indications for Use signature block had K023654 written by hand. It should read K023657.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

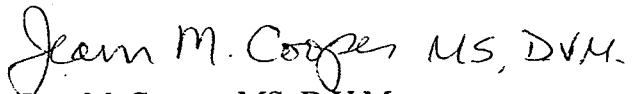
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K023657

Device Name: Ascensia™Contour™ Diabetes Care System

Indications for Use: The ASCENSIA™ CONTOUR™ Blood Glucose Meter is used with ASCENSIA™MICROFILL™ Test Strips and ASCENSIA™MICROFILL™ CONTROL SOLUTIONS for the measurement of glucose in whole blood. The ASCENSIA™ CONTOUR™ Diabetes Care System is an Over-the-Counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

The ASCENSIA™ CONTOUR™ Diabetes Care System is indicated for use with venous, arterial and capillary whole blood samples drawn from the fingertip, palm, forearm, abdomen and thigh.

The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K023654

K 023657

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒

MAY 12 2003

Bayer Diagnostics
ASCENSIA™ CONTOUR™ Diabetes Care System
S&E Summary Page 1 of 2

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: October 28, 2002

Submitter: Bayer Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
(219) 262-6928

Contact: George M. Tancos, RAC
Manager, Regulatory Compliance

Device: Trade/Proprietary Name: ASCENSIA™ CONTOUR™ Diabetes
Care System

Common/Usual Name: Blood Glucose Meter
Document Control Number: K023657

Classification: Division of Clinical Laboratory Devices
Panel – Clinical Chemistry and Toxicology
Classification Code – 75 LFR (Glucose Dehydrogenase, Glucose)

Predicate Devices: ASCENSIA ELITE™ XL Diabetes Care System

Device Description: The ASCENSIA™ CONTOUR™ Diabetes Care System consists of an electrochemical method-based meter and dry reagent sensor (test strips) designed for testing glucose by persons with diabetes or by healthcare professionals in the home or in healthcare facilities.

Intended Use: The ASCENSIA™ CONTOUR™ Diabetes Care System is for the Self-Monitoring of Blood Glucose as an adjunct to the care of person with diabetes.¹

¹ "Consensus Statement on Self-Monitoring of Blood Glucose," Diabetes Care, Vol. 10, No. 1, January-February 1987, pp. 95-99

Technological
Characteristics:

The ASCENSIA™ CONTOUR™ Diabetes Care System employs an amperometric glucose dehydrogenase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. There are 50 test strips in a bottle. Blood glucose results are referenced to plasma glucose. The System has a linear response to glucose from 10-600 mg/dL.

Assessment of
Performance:

An evaluation of the ASCENSIA™ CONTOUR™ Diabetes Care System was studied in house and in a clinical setting by persons with diabetes. The studies demonstrated that users can obtain blood glucose results from alternate puncture sites that are substantially equivalent to finger sticks.

Conclusion:

The results of clinical evaluations of the ASCENSIA™ CONTOUR™ Diabetes Care System demonstrate that the device is equivalent in performance to the predicate devices and suitable for its intended use.